

## REMARKS

Claims 2-19 are presently pending in the case. The claims have not been amended.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

### **Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 2, 4, 6-11, 13, and 15-19 under 35 USC 103(a) as being unpatentable over U.S. Patent 3,809,084 to Hansen (hereinafter Hansen) in view of U.S. Patent 4,022,224 to Saifer et al (hereinafter Saifer et al). The rejection is traversed.

Hansen and Saifer et al do not render independent claim 2, for example, unpatentable. The references do not singly or together teach or suggest all features positively set forth in claim 2. Claim 2 is to an apparatus for producing aerosolized medicament, the apparatus comprising, inter alia, a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide, wherein at least 40 percent by weight of the powder medicament is suspended by gas in a chamber for delivery through a mouthpiece. Hansen and Saifer et al do not disclose, teach or suggest this feature. Accordingly, independent claim 2 is not rendered unpatentable by the references.

Hansen does not disclose the suspension of at least 40 percent of a powder. The Examiner points to column 1 lines 38 to 44 of Hansen in support of the rejection. However, this recitation refers only to the amount of powder in the chamber that is carried to a patient. There is no discussion as to what percentage of the powder in the receptacle makes up this dose.

Saifer et al does not make up for the deficiencies of Hansen in this regard. Saifer et al teaches the advantages of delivering orgotein to a patient to reduce superoxide accumulation caused by smoke inhalation. Though no motivation for doing so is provided, the Examiner is apparently taking the position that it would have been obvious for one of ordinary skill in that art at the time of Applicant's invention to administer orgotein using the device taught by Hansen. Notwithstanding the impropriety of the proposed combination, there remains a lack of teaching

that the resulting administration would meet the "at least 40%" limitation of claim 2. Given the known difficulties often associated with aerosolizing proteins and polypeptides, the Examiner is improperly basing the rejection on pure speculation.

For at least these reasons, Applicant requests withdrawal of the rejection of claim 2 and the claims 4 and 6-10 which depend from claim 2.

Hansen and Saifer et al also fail to render independent claim 11 unpatentable. Claim 11 is to an apparatus for producing aerosolized medicament, the apparatus comprising, inter alia, a reservoir containing a powder medicament to be aerosolized, a chamber comprising an inlet and a mouthpiece, wherein gas may flow into the chamber through the inlet and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament, wherein the volume of the aerosolized medicament is from 9.24 percent to 21.5 percent of the volume of the chamber. Hansen and Saifer et al are completely silent as to this feature. Accordingly, the references do not render claim 11 or claims 13 and 15-19 which depend from claim 11 unpatentable.

The Examiner rejected claims 3 and 12 under 35 USC 103(a) as being unpatentable Hansen and Saifer et al and further in view of U.S. Patent 4,174,712 to Moren (hereinafter Moren). The rejection is traversed.

Claims 3 and 12 depend from claims 2 and 11, respectively. Claims 2 and 11 are not rendered unpatentable by Hansen and Saifer et al, as discussed above. Moren does not make up for the deficiencies of Hansen and Saifer et al. Therefore, claims 2, 3, 11, and 12 are not unpatentable over Hansen, Saifer et al, and Moren.

The Examiner rejected claims 5 and 14 under 35 USC 103(a) as being unpatentable Hansen and Saifer et al and further in view of U.S. Patent 4,534,343 to Nowacki et al (hereinafter Nowacki et al). The rejection is traversed.

Claims 5 and 14 depend from claims 2 and 11, respectively. Claims 2 and 11 are not rendered unpatentable by Hansen and Saifer et al, as discussed above. Nowacki et al does not make up for the deficiencies of Hansen and Saifer et al. Therefore, claims 2, 3, 11, and 12 are not unpatentable over Hansen, Saifer et al, and Nowacki et al.

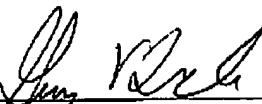
**Conclusion**

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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